IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MALLINCKRODT LLC, MALLINCKRODT INC. and NUVO RESEARCH INC. Plaintiffs, v. TARO PHARMACEUTICAL INDUSTRIES LTD. and TARO PHARMACEUTICALS U.S.A., INC. Defendants.	)	Civil Action No. _____

COMPLAINT

Plaintiffs Mallinckrodt LLC, Mallinckrodt Inc. and Nuvo Research Inc. (collectively "Plaintiffs"), by their undersigned attorneys, for their Complaint against Defendants Taro Pharmaceutical Industries, Ltd. and Taro Pharmaceuticals U.S.A., Inc. (collectively "Taro"), herein allege:

NATURE OF ACTION

1. This is an action for patent infringement under the patent laws of the United States, Title 35 of the United States Code, arising from Taro filing an Abbreviated New Drug Application ("ANDA") with the United States Food and Drug Administration ("FDA") seeking approval to market generic versions of Plaintiffs' pharmaceutical product PENNSAID® prior to the expiration of United States Patent No. 8,217,078 ("the '078 patent"), which covers the use of PENNSAID®.

PARTIES

2. Plaintiff Mallinckrodt LLC is a limited liability company organized and existing under the laws of the State of Delaware, having a place of business at 675 McDonnell Boulevard, Hazelwood, Missouri 63042-2379.

3. Plaintiff Mallinckrodt Inc. is a corporation organized and existing under the laws of the State of Delaware, having a place of business at 675 McDonnell Boulevard, Hazelwood, Missouri 63042-2379.

4. Plaintiff Nuvo Research Inc. is a corporation organized and existing under the laws of Ontario, having a place of business at 7560 Airport Road, Unit 10, Mississauga, Ontario L4T 4H4, Canada.

5. On information and belief, Defendant Taro Pharmaceutical Industries, Ltd. is a corporation organized and existing under the laws of Israel, having a place of business at Italy House, Euro Park, Yakum 60972, Israel. On information and belief, Taro Pharmaceutical Industries, Ltd. is in the business of making and selling generic pharmaceutical products, which it distributes in the State of Delaware and throughout the United States through its subsidiaries, including Taro Pharmaceuticals U.S.A., Inc. On information and belief, Taro Pharmaceutical Industries, Ltd. has previously submitted to the jurisdiction of this Court and has purposefully availed itself of the jurisdiction of this Court by filing lawsuits and asserting counterclaims in lawsuits filed in the United States District Court for the District of Delaware.

6. On information and belief, Defendant Taro Pharmaceuticals U.S.A., Inc. is a corporation organized and existing under the laws of New York, having a principal place of business at 3 Skyline Drive, Hawthorne, New York 10532. On information and belief, Taro Pharmaceuticals U.S.A., Inc., itself and as the agent, wholly-owned subsidiary, and distributor of

Taro Pharmaceutical Industries, Ltd., is in the business of making and selling generic drug products in the State of Delaware and throughout the United States. On information and belief, Taro Pharmaceuticals U.S.A., Inc. has previously submitted to the jurisdiction of this Court and has purposefully availed itself of the jurisdiction of this Court by filing lawsuits and asserting counterclaims in lawsuits filed in the United States District Court for the District of Delaware.

JURISDICTION AND VENUE

7. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

8. This Court has personal jurisdiction over Taro by virtue of, inter alia, its presence in Delaware, having conducted business in Delaware, having availed itself of the rights and benefits of Delaware law, previously consenting to personal jurisdiction in this Court, availing itself of the jurisdiction of this Court, and having engaged in systemic and continuous contacts with the State of Delaware.

9. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391 and 1400(b).

PENNSAID®

10. PENNSAID® was first developed in Canada by Nuvo as a treatment for arthritis, particularly in the knee.

11. PENNSAID® contains the active ingredient diclofenac, a non-steroidal anti-inflammatory drug ("NSAID") that is formulated with dimethyl sulfoxide ("DMSO"), a powerful solvent. PENNSAID® is applied multiple times per day by rubbing the solution onto the skin surrounding the knee. On information and belief, the DMSO in PENNSAID® is an absorption enhancer that allows the diclofenac to absorb through the skin and migrate directly to the source of inflammation. Because PENNSAID® contains what is understood to be an absorption

enhancer, there were early concerns that medications applied to the same area during treatment with PENNSAID® – other NSAIDs, insect repellant, sunscreen, etc. – might also absorb through the skin and present a danger of toxicity.

12. For this reason, the March 13, 2003 PENNSAID® Canadian Foreign Product Monograph advised physicians at the time to inform patients not to apply any other medication to the treated area during the course of treatment.

13. This limitation presented problems during treatment with PENNSAID® because the most frequently noted adverse drug reaction in patients treated with PENNSAID® was application site skin irritation and dermatitis. Application site skin irritation and dermatitis are regularly treated with topical medications, particularly topical medications called corticosteroids, to relieve those conditions. Because the monograph instructed that topical medications were contraindicated during the course of treatment with PENNSAID®, patients that experienced these adverse reactions either had to discontinue application of PENNSAID® or leave the application site skin irritation and dermatitis untreated.

14. During drug development, the Nuvo researchers who became the inventors of the '078 patent surprisingly discovered that a second medication can be safely applied to the application site during treatment with PENNSAID® if the treated area is first allowed to dry. The inventors discovered that patients experiencing application site skin irritation and dermatitis can be safely treated with a second topical medication, for example corticosteroids, provided that the area treated with PENNSAID® is allowed to dry before the second topical medication is applied.

15. In 2009, Mallinckrodt LLC licensed Nuvo's pending patent applications and know-how concerning PENNSAID® patents and sought approval from the FDA to market

PENNSAID® in the United States. The FDA approved Mallinckrodt's New Drug Application No. N020947 ("the PENNSAID® NDA") for diclofenac sodium topical solution 1.5%, under the trade name PENNSAID®, on November 4, 2009.

16. As a part of the regulatory process for obtaining approval of the PENNSAID® NDA, Mallinckrodt Inc. was required by the FDA to submit a proposed label for the drug. *See* 21 C.F.R. § 201.56(b). The label for PENNSAID® instructs physicians and patients, inter alia, about the proper dosage and administration of PENNSAID®.

17. The label for PENNSAID® indicates, inter alia, that the most common adverse events associated with using diclofenac sodium topical solution are application site reactions. Because of the discovery that a second medication can be safely applied during treatment with PENNSAID® if the area treated with PENNSAID® is allowed to dry, the label for PENNSAID® instructs physicians and patients to apply PENNSAID® to the knee and then allow the area to dry before applying another topical medication.

18. A physician familiar with the application of topical medications such as PENNSAID® would therefore understand that topical medications used to treat application site reactions would be subject to the label's instruction to allow the treated area to dry before applying another topical medication.

19. Plaintiffs have educated prescribing physicians regarding the use of PENNSAID®. Physicians are informed that a common side effect of the use of such a diclofenac sodium topical solution 1.5% is application site skin irritation and dermatitis. Physicians are told that an appropriate method for treating the resulting skin irritation is to wait until the application site is dry after application of PENNSAID® and then apply a topical medication including, but not limited to, a corticosteroid. Further, on information and belief, it is the standard of care for

physicians to treat application site skin irritation and dermatitis by using topical corticosteroid drug products. One or more claims of the '078 patent cover the method of applying diclofenac sodium topical solution 1.5%, waiting for the treated area to dry, and then applying a second topical medication.

THE PATENT-IN-SUIT

20. The Nuvo researchers who discovered that a second medication can be safely applied during treatment with PENNSAID® filed patent applications beginning in March 2009 to protect their inventions.

21. On July 10, 2012 the United States Patent and Trademark Office issued the '078 patent, entitled "Treatment of Pain with Topical Diclofenac." The '078 patent was assigned to Nuvo Research Inc. by inventors Jagat Singh, Joseph Zev Shainhouse, Bradley S. Galer, Robert Dominic King-Smith, Lisa Marie Grierson, Maria Burian, Jonathan Wilkin, Edward T. Kisak, and John M. Newsam. Nuvo Research Inc. granted Mallinckrodt LLC an exclusive license under the '078 patent with respect to, inter alia, topical diclofenac products known as PENNSAID®. A copy of the '078 patent is attached hereto as Exhibit A.

22. The '078 patent is listed for PENNSAID® in the Patent and Exclusivity Information Addendum of the FDA's publication *Approved Drug Products with Therapeutic Equivalence Evaluations* ("the Orange Book"). The Patent Use Code listed in the Orange Book for the PENNSAID® product is "Use of topical diclofenac on the knee and a second topical medication on the same knee."

TARO'S ANDA

23. On information and belief, Taro submitted ANDA No. 203818 ("the Taro ANDA") to the FDA, pursuant to 21 U.S.C. § 355(j), seeking approval to market diclofenac

sodium topical solution 1.5% before the '078 patent expires. The diclofenac sodium topical solution described in the Taro ANDA is herein referred to as the "Taro Product."

24. The Taro ANDA refers to and relies upon the PENNSAID® NDA and contains data that, according to Taro, demonstrate the bioequivalence of the Taro Product and PENNSAID®.

25. On or about February 11, 2013, Taro sent to Plaintiffs a letter (the "Taro Notification") that was received on or about February 12, 2013 stating that Taro had included a certification in the Taro ANDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), that the '078 patent is invalid or will not be infringed by the commercial manufacture, use, or sale of the Taro Product (the "Taro Paragraph IV Certification").

COUNT I
TARO'S DIRECT INFRINGEMENT OF U.S. PATENT NO. 8,217,078 UNDER 35 U.S.C. § 271(e)(2)(A)

26. Plaintiffs reallege and incorporate by reference the allegations of paragraphs 1-25 of this Complaint.

27. Taro has infringed the '078 patent, pursuant to 35 U.S.C. § 271(e)(2)(A) by submitting the Taro ANDA, by which Taro seeks approval from the FDA to engage in the commercial manufacture, use, offer to sell, sale, or importation of the Taro Product prior to the expiration of the '078 patent.

28. Plaintiffs will be substantially and irreparably harmed if Taro is not enjoined from infringing the '078 patent.

29. Plaintiffs have no adequate remedy at law.

COUNT II
TARO'S INDUCEMENT OF INFRINGEMENT OF U.S. PATENT NO. 8,217,078 UNDER 35 U.S.C. § 271(b)

30. Plaintiffs reallege and incorporate by reference the allegations of paragraphs 1-29 of this Complaint.

31. On information and belief, approval of the Taro ANDA is substantially likely to result in the commercial use, manufacture, offer for sale and/or sale, or inducement thereof, of a drug product that is marketed and sold for use in a method claimed in one or more claims of the '078 patent, immediately or imminently upon approval of the Taro ANDA.

32. The FDA requires Taro's proposed label for the Taro Product to contain the same prescribing, dosage and administration, and side effect information as found on the PENNSAID® label. *See* 21 C.F.R. § 314.94(8)(iv).

33. On information and belief, Taro's proposed label for the Taro Product will instruct patients and physicians to apply the Taro Product to the knee and then allow the area to dry before applying another topical medication. On information and belief, Taro's proposed label for the Taro Product will inform patients and physicians that the most common side effect of using a diclofenac sodium topical solution 1.5%, including the Taro Product, is application site skin irritation. On information and belief, Taro is aware that patients and physicians using this product will use another topical medication to treat application site skin irritation and that the application of a second topical medication would be subject to the label's instruction to allow the treated area to dry before application. On information and belief, Taro will be marketing the Taro Product with specific intent, and/or with desire, to actively induce, aid and abet infringement of the '078 patent. Taro knows or reasonably should know that its proposed conduct will induce infringement of the '078 patent.

34. On information and belief, Taro's generic marketing practices include listing generic products on its website and referring physicians and patients to a corresponding brand name product. On information and belief, Taro intends to do the same for the Taro Product, namely Taro intends to list its generic product and refer patients to Plaintiffs' product, PENNSAID®. On information and belief, such marketing practices are likely to lead physicians prescribing, and patients using, a generic diclofenac sodium topical solution product to infer that recommendations regarding the use of PENNSAID®, including recommendations relating to the treatment of side effects stemming from the use of PENNSAID®, also apply to the Taro Product.

35. On information and belief, the acts of infringement alleged above are and have been deliberate and willful.

36. Plaintiffs will be substantially and irreparably harmed if Taro is not enjoined from inducing infringement of the '078 patent.

37. Plaintiffs have no adequate remedy at law.

COUNT III
EXCEPTIONAL CASE WITH RESPECT TO TARO UNDER 35 U.S.C. § 285

38. Plaintiffs reallege and incorporate by reference the allegations of paragraphs 1-37 of this Complaint.

39. This case is an exceptional one, and Plaintiffs are entitled to an award of attorneys' fees under 35 U.S.C. § 285 in light of Taro's conduct.

PRAYER FOR RELIEF

WHEREFORE, Mallinckrodt Inc., Mallinckrodt LLC, and Nuvo Research Inc. pray for a judgment in their favor and against Defendants Taro Pharmaceutical Industries, Ltd. and Taro Pharmaceuticals U.S.A., Inc., and respectfully request the following relief:

A. A judgment declaring that Taro has directly infringed and will induce infringement of U.S. Patent No. 8,217,078;

B. A judgment pursuant to 35 U.S.C. § 271(e)(4)(B) preliminarily and permanently enjoining Taro, its officers, agents, servants, and employees, and those persons in active concert or participation with any of them, from manufacturing, using, offering to sell, or selling the Taro Product within the United States, or importing the Taro Product into the United States, prior to the expiration date of the '078 patent;

C. A judgment ordering that pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of ANDA No. 203818 under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)) shall not be earlier than the expiration date of the '078 patent, including any extensions;

D. If Taro commercially manufactures, uses, offers to sell, or sells the Taro Product within the United States, or imports the Taro Product into the United States, prior to the expiration of the '078 patent, including any extensions, a judgment awarding Plaintiffs monetary relief together with interest;

E. A judgment declaring that Taro has directly infringed and will induce infringement of U.S. Patent No. 8,217,078;

F. A judgment pursuant to 35 U.S.C. § 271(e)(4)(B) preliminarily and permanently enjoining Taro, its officers, agents, servants, and employees, and those persons in active concert or participation with any of them, from manufacturing, using, offering to sell, or selling the Taro Product within the United States, or importing the Taro Product into the United States, prior to the expiration date of the '078 patent;

G. A judgment ordering that pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of ANDA No. 204132 under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)) shall not be earlier than the expiration date of the '078 patent, including any extensions;

H. If Taro commercially manufactures, uses, offers to sell, or sells the Taro Product within the United States, or imports the Taro Product into the United States, prior to the expiration of the '078 patent, including any extensions, a judgment awarding Plaintiffs monetary relief together with interest;

I. Attorneys' fees in this action as an exceptional case pursuant to 35 U.S.C. § 285;

J. Costs and expenses in this action; and

K. Such other relief as the Court deems just and proper.

/s/ Frederick L. Cottrell, III

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